Amendment

In the Claims

1. (currently amended) A milnacipran formulation that provides delayed ~~or~~ and extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to ~~one or more immediate release milnacipran~~ side effects resulting from administration of the same dose of milnacipran administered in an immediate release formulation.

2. (original) The milnacipran formulation according to Claim 1, wherein the side effect is nausea.

3. (previously presented) The milnacipran formulation according to Claim 1, wherein the side effects are selected from the group consisting of vomiting, headache, tremulousness, anxiety, panic attacks, palpitations, urinary retention, orthostatic hypotension, diaphoresis, chest pain, rash, weight gain, back pain, constipation, vertigo, increased sweating, agitation, hot flushes, tremors, fatigue, somnolence, dyspepsia, dysoria, nervousness, dry mouth, abdominal pain, irritability, and insomnia.

4. (currently amended) The milnacipran formulation according to Claim 1 wherein ~~having a milnacipran release profile that is characterized by release of~~ less than approximately 10% of the total milnacipran dose ~~over a period up to four hours, followed by a slow or extended drug release~~ is released in one hour when the formulation is subjected to *in vitro* dissolution in 0.1 N HCl..

5. (currently amended) The milnacipran formulation according to Claim 4 wherein the ~~defined~~ extended release of milnacipran is over a period of time that is between approximately four and approximately twenty-four hours.

6. (original) The milnacipran formulation according to Claim 1 providing milnacipran blood plasma levels that are characterized by T_{max} at 4-10 hours, and C_{max} below approximately 3000 ng/ml.

7. (original) The milnacipran formulation according to Claim 6 providing milnacipran blood plasma levels that are characterized by C_{max} below approximately 2000 ng/ml.

8. (original) The milnacipran formulation according to Claim 6 providing milnacipran blood plasma levels that are characterized by C_{max} below approximately 1000 ng/ml.

9. (original) The milnacipran formulation according to Claim 1 further comprising at least one other active compound selected from the group consisting of analgesics, anti-inflammatory drugs, antipyretics, antidepressants, anti epileptics, antihistamines, antimigraine drugs, antimuscarinics, anxioltyics, sedatives, hypnotics, antipsychotics, bronchodilators, anti asthma drugs, cardiovascular drugs, corticosteroids, dopaminergics, electrolytes, gastro-intestinal drugs, muscle relaxants, nutritional agents, vitamins, parasympathomimetics, stimulants, anorectics, and anti-narcoleptics.

10. (original) The milnacipran formulation according to Claim 9 comprising compounds selected from the group consisting of aceclofenac, acetaminophen, adomexetine, almotriptan, alprazolam, amantadine, amcinonide, aminocyclopropane, amitriptyline,

amolodipine, amoxapine, amphetamine, aripiprazole, aspirin, atomoxetine, azasetron, azatadine, beclomethasone, benactyzine, benoxaprofen, bermoprofen, betamethasone, bicifadine, bromocriptine, budesonide, buprenorphine, bupropion, buspirone, butorphanol, butriptyline, caffeine, carbamazepine, carbidopa, carisoprodol, celecoxib, chlordiazepoxide, chlorpromazine, choline salicylate, citalopram, clomipramine, clonazepam, clonidine, clonitazene, clorazepate, clotiazepam, cloxazolam, clozapine, codeine, corticosterone, cortisone, cyclobenzaprine, cyproheptadine, demexiptiline, desipramine, desomorphine, dexamethasone, dexanabinol, dextroamphetamine sulfate, dextromoramide, dextropropoxyphene, dezocine, diazepam, dibenzepin, diclofenac sodium, diflunisal, dihydrocodeine, dihydroergotamine, dihydromorphine, dimetacrine, divalproxex, dizatriptan, dolasetron, donepezil, dothiepin, doxepin, duloxetine, ergotamine, escitalopram, estazolam, ethosuximide, etodolac, femoxetine, fenamates, fenoprofen, fentanyl, fludiazepam, fluoxetine, fluphenazine, flurazepam, flurbiprofen, flutazolam, fluvoxamine, frovatriptan, gabapentin, galantamine, gepirone, ginko bilboa, granisetron, haloperidol, huperzine A, hydrocodone, hydrocortisone, hydromorphone, hydroxyzine, ibuprofen, imipramine, indiplon, indomethacin, indoprofen, iprindole, ipsapirone, ketaserin, ketoprofen, ketorolac, lesopitron, levodopa, lipase, lofepramine, lorazepam, loxapine, maprotiline, mazindol, mefenamic acid, melatonin, melitracen, memantine, meperidine, meprobamate, mesalamine, metapramine, metaxalone, methadone, methadone, methamphetamine, methocarbamol, methyldopa, methylphenidate, methylsalicylate, methysergid(e), metoclopramide, mianserin, mifepristone, milnacipran, minaprine, mirtazapine,

moclobemide, modafinil, molindone, morphine, morphine hydrochloride, nabumetone, nadolol, naproxen, naratriptan, nefazodone, neurontin, nomifensine, nortriptyline, olanzapine, olsalazine, ondansetron, opipramol, orphenadrine, oxaflozane, oxaprazin, oxazepam, oxitriptan, oxycodone, oxymorphone, pancrelipase, parecoxib, paroxetine, pemoline, pentazocine, pepsin, perphenazine, phenacetin, phendimetrazine, phenmetrazine, phenylbutazone, phenytoin, phosphatidylserine, pimozide, pirlindole, piroxicam, pizotifen, pizotyline, pramipexole, prednisolone, prednisone, pregabalin, propanolol, propizepine, propoxyphene, protriptyline, quazepam, quinupramine, reboxitine, reserpine, risperidone, ritanserin, rivastigmine, rizatriptan, rofecoxib, ropinirole, rotigotine, salsalate, sertraline, sibutramine, sildenafil, sulfasalazine, sulindac, sumatriptan, tacrine, temazepam, tetrabenozine, thiazides, thioridazine, thiothixene, tiapride, tiasipirone, tizanidine, tofenacin, tolmetin, toloxatone, topiramate, tramadol, trazodone, triazolam, trifluoperazine, trimethobenzamide, trimipramine, tropisetron, valdecoxib, valproic acid, venlafaxine, viloxazine, vitamin E, zimeldine, ziprasidone, zolmitriptan, zolpidem, zopiclone and isomers, salts, and combinations thereof.

11. (original) The milnacipran formulation according to Claim 1, wherein the milnacipran is in the form of a therapeutically equivalent dose of dextrogyral or levrogyral enantiomers of the milnacipran or pharmaceutically acceptable salts thereof.

12. (original) The milnacipran formulation according to Claim 1, wherein the milnacipran is in the form of a therapeutically equivalent dose of a mixture of milnacipran enantiomers or pharmaceutically acceptable salts thereof.

13. (canceled)

14. (currently amended) The milnacipran formulation according to Claim 1, wherein the milnacipran is in the form of a therapeutically equivalent dose of para-hydroxy-milnacipran (F2782), individual enantiomers of para-hydroxy-milnacipran, mixtures of enantiomers of para-hydroxy-milnacipran, or pharmaceutically acceptable salts thereof.

15. (currently amended) The milnacipran formulation according to Claim 1 ~~comprising an enteric coating~~ wherein the delayed release is achieved by coating an extended release dosage form with at least one delayed release polymer which is insoluble in the acid environment of the stomach and is soluble in the neutral environment of the small intestine..

16. (original) The milnacipran formulation according to Claim 1, wherein the administrable milnacipran unit dose is from 25 to 500 mg.

17. (original) The milnacipran formulation according to Claim 1, wherein the administrable milnacipran unit dose is from 200 to 500 mg.

18. (original) The formulation according to Claim 9 comprising 25 to 500 mg milnacipran and 100 to 600 mg modafinil.

19. (Canceled)

20. (original) A kit comprising the milnacipran formulation of Claim 1.

21. (original) The kit of Claim 20 comprising different dosage units of milnacipran to allow for dosage escalation.

22. (original) The kit of Claim 20 comprising instruction on taking the formulation once daily before bedtime.

23. (canceled)

24. (canceled)

25. (new) The composition according to claim 1, wherein less than approximately 10% of the total milnacipran dose is released in two hours when the formulation is subjected to *in vitro* dissolution in 0.1 N HCl.

26. (new) The formulation according to Claim 1 wherein the milnacipran rise in blood plasma upon administration to a human subject is delayed for at least half-an-hour when compared to that of the same dose of milnacipran administered in an immediate release formulation.